DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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February 4, 2000

E. Edward Kavanaugh
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Washington, D.C. 20036-4702

Re: Over-the-Counter Drug Labeling (Docket No. 99P-4617/CP1)

Dear Mr. Kavanaugh:

This letter is in response to the petition submitted on October 22, 1999, on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA). The petition, submitted under 21 CFR 10.30, requests a two-year extension of time for compliance with the agency's recently published final rule on the labeling of over-the-counter (OTC) drug products. *See* 64 FR 13254 (Mar. 17, 1999). The final rule establishes a standardized format for presenting required drug labeling information. The rule is intended to assist consumers in reading and understanding OTC drug labeling, in selecting among various products, and in using these products safely and effectively.

The rule went into effect on May 16, 1999.[1] However, for the large majority of products, compliance with the final rule is not required until, at the earliest, May 16, 2001 (the "primary implementation date"). 64 FR at 13274. CTFA requests an extension of this date to May 16, 2003.

CTFA argues that the additional time is needed to resolve several outstanding issues, including "an appropriate small package exemption" and the need to "harmonize" the labeling of products that must meet both drug and cosmetic requirements. CTFA Petition ("Pet.") at 7-8. Many of the issues raised by CTFA were also raised in a petition submitted by the Consumer Healthcare Products Association (CHPA) on October 1, 1999 (Docket No. 98N-0337/CP2). Both petitions requested additional time to address the issues of trade dress, columns, single use and convenience packages, extended text labeling, small packages (including the issue of type size), and the submission of exemption requests under 21 CFR 201.66(e).

A two-year extension, according to CTFA, will allow the industry to continue its dialogue on these issues and ensure fair implementation of the final rule for cosmetic-drug products. The petition also states that this extension would not harm the public health.

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[1]On April 15, 1999 (64 FR 18571), the agency published a correction to the effective date of the final rule.

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Because the petitions substantially overlap, and seek essentially the same relief, the agency incorporates herein the response provided to CHPA. In this response, the agency will focus only on issues not raised in the CHPA petition: (1) whether a stay is needed to discuss a categorical small package exemption is needed; and (2) whether a stay is needed to discuss ways to "harmonize" the new "Drug Facts" labeling with existing cosmetic labeling.

The agency has carefully considered the petition, and all relevant information related to it. For the reasons discussed below, and for the reasons discussed in the response to the petition filed by CHPA (*see* attached), the agency is granting CTFA's petition in part and denying it in part. The agency, in an upcoming notice in the Federal Register, will publish notice of an amendment to the implementation plan extending the primary implementation date by one year, to May 16, 2002 (and the corresponding implementation date for low volume products to May 16, 2003).[2]

I. Analysis

Cosmetic-drug products, as CTFA acknowledges, must meet all applicable labeling requirements for both cosmetic products and drug products. CTFA believes, however, that the final rule on OTC drug labeling fails to recognize the additional labeling burden faced by cosmetic-drug products. Pet. at 2. CTFA also argues that the agency has no evidence with which to support the application of the new OTC labeling format to cosmetic-drug products and, in particular, to cosmetic-drug products that are sold without specific dosage limitations. The inherent safety of the latter category, according to CTFA, makes the use of new format an "unnecessary imposition." Pet. at 2-3. Nevertheless, CTFA states that its members will make a good faith effort to comply with the new rule, provided additional time is given to address several issues. Pet. at 3.

The two issues not fully addressed by the agency in its response to the CHPA petition are: (1) CTFA's request for a categorical small package exemption, and (2) CTFA's inquiry regarding ways to harmonize the new OTC drug labeling requirements with cosmetic labeling requirements.

As a preliminary matter, the agency notes that CTFA is not questioning the need for cosmetic-drug products to carry FDA-required labeling. Indeed, the association's members intend to continue to include all FDA-required drug labeling with their products. Pet. at 5. CTFA is, however, contesting the need for FDA to require the placement of this information in a new, standardized format.

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[2]The implementation plan for the final rule (64 FR at 13274) provides one additional year (to May 16, 2002) for products with annual sales of less than $25,000.

The new format establishes a clear, easy-to-read presentation that lists the required information in a logical hierarchy, with simple headings and subheadings to introduce major sections of the labeling. The format also includes minimum type size and graphical standards, to help ensure that consumers are able to read the required labeling comfortably, from beginning to end. And, the format is designed to allow consumers to compare similar products side-by-side, to help them recognize differences among products, and to help them select the best product to meet their needs. CTFA agrees that required information must be presented on cosmetic-drug labeling; CTFA disagrees, however, with having to present this information in the new, easy-to-read format.

A. Categorical Exemption for Small Packages

In its comments to the proposed rule, CTFA argued that the agency should exclude from the rule cosmetic-drug products sold without dosage limitations (*i.e.*, sunscreens, antidandruff shampoos, skin protectants, antimicrobial soaps and washes, and antiperspirant/deodorant products). For the reasons outlined in the final rule, the agency declined to accept CTFA's proposal. 64 FR at 13268-70. As a result, CTFA argues that "an objective small package exemption standard" is now vitally important, to minimize "the negative impact of certain of the new format requirements" on these and other products. Pet. at 7-8. CTFA's proposed small package standard — once triggered — would exempt products *in toto* from the new labeling format. Pet. at 8.

For the reasons discussed in the preamble to the final rule, the agency continues to believe that a *blanket* exemption for small packages is neither necessary nor appropriate. *See* 64 FR at 13267-68; *see also* 64 FR 13282-83 (finding that only about 8 percent of existing products may need to increase package size to accommodate the new labeling). This decision is consistent with the agency's overall goal of ensuring that all OTC drug labeling, irrespective of package size, is clear and readable and is "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. 352(c). It is also consistent with the agency's estimate that any package size changes that would be needed as a result of this rule would either be very limited (*e.g.*, increasing the dimensions of an existing package by a small fraction), or could be accomplished by integrating commonly used techniques, such as the addition or extension of a fifth panel or the use of a placard and bubble-pack. *See* 64 FR at 13268, 13283. Further, as discussed in the response to CHPA's petition (attached at II.D), the agency intends to publish shortly a draft guidance that will include information on how manufacturers may seek a limited deferral of time for the purpose of completing a change in packaging to meet the requirements of the rule.

The agency also stands by its decision not to exempt from the final rule the five categories of OTC drug products identified by CTFA which are often marketed for both drug and cosmetic uses, and which usually do not bear a "dosage limitation." *See generally* 64 FR at

13268-70. The final rule sets forth the reasoning in support of the use of a standardized format for all drug products that are sold OTC to lay consumers. Also, and as the agency emphasized in the final rule, the importance of the labeling cannot be minimized – even within the categories identified by CTFA for exemption. *Id.*

For example, certain sunscreen ingredients have the potential to cause photo-allergenicity and, accordingly, bear warnings to stop use and speak to a doctor if a rash or irritation develops. Skin protectant ingredients which may not require special care in cosmetic uses (*e.g.*, petrolatum used to remove make-up), may require special care when intended for a drug use (*e.g.*, petrolatum as a skin protectant for the temporary protection of minor cuts, scrapes, and burns).[3] Antiperspirant products, which contain aluminum salts, include warnings not to apply the products to broken skin, and to discontinue use if a rash or irritation develops. Some dandruff shampoos may promote sun sensitivity, while others include specific language when labeled for use in treating seborrheic dermatitis or psoriasis. Some antimicrobial washes contain substantial amounts of alcohol and may be required to include flammability warnings. Antiseptic handwash drug products instruct not to use in the eyes and to discontinue use if irritation and redness develops, and to contact a doctor if the condition persists for more than 72 hours.

The categories of cosmetic-drug products identified by CTFA, as with all other OTC drug categories, include important labeling information that must be presented in a manner that is likely to be read and understood. The placement of this and other required information in a standard format is expected to minimize the complexity of the information and, in turn, increase the likelihood that consumers will read and focus on it. The format also will provide consumers with an important tool for comparing products to help them select an appropriate product to meet their needs. *See generally* 64 FR at 13254-55; 62 FR at 9040. For example, "Drug Facts" labeling will help consumers differentiate between products intended solely to provide a cosmetic effect (such as a non-fluoride toothpaste or a deodorant) and products that are intended to provide both a cosmetic and a drug effect (such as a flouride-containing toothpaste or an antiperspirant-deodorant).

Finally, the agency recognizes that there may be specific ingredients for which streamlined labeling requirements can be explored, to help allow for the continued marketing of these ingredients in small packages. As discussed in the final rule, the agency will consider the possibility of ingredient or category-specific small package exceptions, but only in the context of a medical and scientific review. *See* 64 FR at 13270 (noting that the agency would identify possible monograph-based accommodations for small packages for products that have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable

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[3]The application of a skin protectant over a deep wound or puncture or over an infection or laceration can lead to serious complications. Serious wounds, punctures, or infected lesions, if placed under a sealed, greasy cover may become macerated and further inflamed.

public health benefit, require no specific dosage limitation, and require few specific warnings and no general warnings (*e.g.*, pregnancy or overdose warnings)). Ingredient or category-specific arguments, such as those raised by CTFA, are best addressed within the OTC drug monographs, where the safety and effectiveness of each ingredient in the OTC Drug Review is being carefully evaluated.

Three of the five categories identified by CTFA – antiperspirants, skin protectants, and topical antimicrobial soaps and washes – are not the subject of final monographs. The agency will carefully consider the ingredients in each of these categories as it finalizes the monographs, and will seek to identify ways, where appropriate, to accommodate those ingredients that are typically marketed in small packages.

One category (sunscreens) is the subject of a monograph that published after the labeling rule. *See* 64 FR 27666 (May 21, 1999). The sunscreen monograph included several accommodations for products that are customarily packaged in small containers, are intended to be applied to limited areas of the face, and otherwise meet the characteristics discussed in the labeling rule. 64 FR 27666, 27689 (May 21, 1999). Further, in a letter dated October 1, 1999, the agency informed CTFA that the effective date for implementing the monograph for OTC sunscreen drug products will be extended to December 2002, and that the agency would consider additional accommodations as appropriate as it develops a comprehensive UVA-UVB monograph for sunscreens.

Only one category (antidandruff shampoo) is the subject of a final monograph that pre-dated publication of the OTC labeling rule. To the extent such products raise small package concerns, the agency would consider format or content accommodations through a petition to amend the monograph under 21 CFR 330.10(a)(12).

In sum, implementation of the final labeling rule need not be delayed for further consideration of a categorical or blanket small package exemption, as requested by CTFA. The agency carefully considered the needs of small package products in the final rule. The rule includes format specifications that will allow most products to bear the new "Drug Facts" labeling without requiring a change in packaging. Many of the remaining products will require only small changes in packaging to meet the requirements of the rule. With the extension of time provided in response to this petition, most products will continue to have a substantial period of time for compliance with the rule. For some specific products, even more time may be obtained through the deferral process.

B. Harmonization with Cosmetic Labeling Requirements.

The petition includes two examples to suggest that additional time is needed to allow for discussion of ways to harmonize OTC drug labeling requirements with cosmetic labeling

requirements. The first involves the listing of inactive ingredients in OTC drug products, now required under section 502(e) of the Federal Food, Drug, and Cosmetic Act (as amended by section 412 of the 1997 FDA Modernization Act). The second, which raises a type size issue, is addressed in the response to the CHPA response (*see* attached at II.C).

The final OTC drug labeling rule specifies a heading for the listing of inactive ingredients and includes several requirements for the presentation of this information. *See* 21 CFR 201.66(c)(8). Section 201.66(c)(8) also describes how to list the inactive ingredients in an OTC drug that is also a cosmetic product. Thus, an OTC cosmetic-drug product may bear one consolidated ingredient list.

CTFA notes, however, that the agency's cosmetic labeling regulations provide many different ways to present cosmetic ingredient information, and that the agency failed to include at least one of those ways in the OTC labeling rule – namely, the use of an off–the-label declaration of ingredients on a "padded sheet" or "leaflet," if the product meets several specific conditions. 21 CFR 701.3(i).

The agency declined to include this provision because it conflicts with section 502(e) of the Act, which provides that a drug is misbranded if its label does not bear inactive ingredient information on the outside container of the retail package. Section 701.3(i) also conflicts with the general approach of the final labeling rule of providing all required information in one continuous "Drug Facts" panel.

CTFA suggests in its petition that the agency wholly ignored the dual labeling concerns of the cosmetic-drug industry. On the contrary, the agency carefully considered ways to avoid duplicative labeling for such products. In particular, with respect to the ingredient listing, the agency incorporated as many of the cosmetic labeling approaches authorized under 21 CFR 701.3 as possible, while still maintaining consistency with statutory labeling requirements and the intent of the final rule. For example, 21 CFR 201.66(c)(8) incorporates by reference sections 701.3(a) and (f), as alternative ways of listing the inactive ingredients (*i.e.*, in descending order of predominance or grouped).

The agency is open to further discussion on ways to address CTFA's dual labeling concerns. The agency does not believe, however, that the petition provides a basis for delaying implementation of the final labeling rule for this purpose.

II. Conclusions

CTFA petitioned the agency seeking an extension of time to discuss several issues. According to the petition, small package issues, the exemption/deferral process, trade dress and light-on-dark printing, and the need for harmonization with existing cosmetic requirements, are

of particular importance to CTFA's members.

As discussed in the response to CHPA, the agency will provide additional guidance on the exemption and deferral process, which will include information of relevance to manufacturers who find they must change their packaging to comply with the rule. The agency has already resolved the trade dress and light-on-dark printing issue through a technical amendment, and has issued a draft guidance on the use of columns, which is also expected to help some small package products. The agency will continue to evaluate ways to convey required information as efficiently and concisely as possible. The agency also is committed to identifying within the monograph process accommodations for small package products within the categories identified by CTFA. The agency continues to find, however, that there is ample basis to decline to exclude the five categories suggested by CTFA from the new format requirements.

Finally, for the reasons outlined more fully in response to the petition submitted by CHPA, the agency will take necessary steps to extend the primary implementation date by one year, to May 16, 2002 (and the corresponding date for low volume products to May 16, 2003).

The agency has worked closely with CTFA to help ensure that OTC cosmetic-drug product labeling is legible and that the final rule is appropriate for the marketplace. We look forward to continuing to have candid, productive discussions, and to working with CTFA toward the shared goal of providing consumers with clear, concise, easy-to-read OTC labeling.

Sincerely yours,

William Hubbard

William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

cc: Bruce N. Kuhlik
Covington & Burling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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February 4, 2000

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Re: Over-the-Counter Drug Labeling (Docket No. 98N-0337/CP2)

Dear Messrs. Kuhlik and Labson:

This letter is in response to the petition submitted on October 1, 1999, on behalf of the Consumer Healthcare Products Association (CHPA). The petition, submitted under 21 CFR 10.30, requests a two-year extension of time for compliance with the agency's final rule on the labeling of over-the-counter (OTC) drug products, 21 CFR 201.66. *See* 64 FR 13254 (Mar. 17, 1999). The rule established a standardized format for presenting required OTC drug labeling information. It is intended to assist consumers in reading and understanding OTC drug labeling, in selecting among various products, and in using these products safely and effectively.

The rule went into effect on May 16, 1999.[1] However, for the large majority of products, compliance with the rule is not required until, at the earliest, May 16, 2001 (the "primary implementation date"). *See* 64 FR at 13274.

CHPA requests a two-year extension of the primary implementation date to May 16, 2003. Also, for those products that must immediately begin to comply with the rule (namely, OTC drug products approved after May 16, 1999, under new drug or abbreviated new drug applications), CHPA requests a stay of the rule "until FDA resolves currently open implementation issues and companies are given sufficient time to incorporate FDA's clarification into the label . . . ." CHPA Petition ("Pet.") at 3.

The primary basis for the petition is the claim that "[c]ritical issues concerning the label formatting under the new rule are unresolved," and that companies cannot begin converting to the new format until these issues are resolved. Pet. at 7. As noted in the petition, the agency's economic impact analysis in support of the final rule generally assumes a 2-year implementation

[1]On April 15, 1999, the agency published a correction to the effective date of the rule (64 FR 18571).

period. Pet. at 11 (*citing* 64 FR at 13272). Because CHPA asserts that manufacturers have been hindered from moving forward with the redesign of their labeling, the petition argues that FDA must extend the primary implementation date. Otherwise, according to CHPA, the agency's economic assumptions in support of the rule are no longer valid. Pet. at 11-12.

The petition lists the following "open" issues:

- the use of columns in labeling
- protection of "trade dress"
- the use of type sizes smaller than 6.0 points
- the labeling of single use and convenience packages
- the use of "extended text labeling" and
- the use of the exemption process under 21 CFR 201.66(e)

According to CHPA, the industry raised these issues in comments to the proposed rule, or immediately after publication of the final rule, but the issues have remained unresolved. Pet. at 2. The petition also states that the final rule included several "new elements" that require further discussion with the agency, such as the placement of a telephone number in the required "Drug Facts" panel and the use of "Drug Facts (continued)" labeling. Pet. at 3.

To account for the time that CHPA claims has been "lost," as well as the time CHPA expects will be required to resolve these issues, the petition seeks a two-year extension of the primary implementation date, as well as the stay described above.

The agency has carefully considered the petition, and all relevant information related to it. For the reasons discussed below, the agency is denying the petition in part and granting it in part. In an upcoming issue of the Federal Register, FDA will publish notice of an amendment to the implementation plan to extend the primary implementation date by one year, to May 16, 2002 (and the corresponding implementation date for low volume products to May 16, 2003[2]). The request for a stay of the rule, for products marketed under new drug or abbreviated new drug applications approved after May 16, 1999, is denied.

I. Procedural History

FDA has been considering the need for OTC drug labeling readability standards for nearly ten years. In 1990 the Pharmacists Planning Service (PPS) petitioned the agency to set print size and print style standards for OTC drug labeling to improve readability (Docket No. 90P-0201). On March 6, 1991, FDA published the PPS petition in the Federal Register and

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[2]The implementation plan for the final rule (64 FR at 13274) provides one additional year (to May 16, 2002) for products with annual sales of less than $25,000.

solicited comments from the public (44 FR 9363).

On March 25, 1991, CHPA (then known as the Nonprescription Drug Manufacturers Association) issued voluntary Label Readability Guidelines to help address consumer demand for improved OTC drug labeling. On April 9, 1991, FDA extended the comment period on its March 6, 1991, notice, to allow the public to comment on the CHPA Guidelines.

On August 16, 1995, FDA published a notice of public hearing under 21 CFR part 15 and requested additional comments on the presentation of OTC drug labeling (60 FR 42578; Docket No. 95N-0259). The public hearing, held on September 29, 1995, included testimony from several experts on label readability, testimony from a representative of the National Consumers League on OTC drug readability, and testimony from CHPA and The Cosmetic, Toiletry, and Fragrance Association (CTFA).

On February 27, 1997, FDA published a proposed rule to establish standardized format and content requirements for OTC drug labeling (62 FR 9024; Docket Nos. 96N-0420, 95N-0259, 92N-454A, and 90P-0201). On May 8, 1997, FDA held a public feedback meeting with industry and other interested persons to discuss the proposed rule. On June 19, 1997, FDA extended the comment period on the proposed rule to October 6, 1997 (62 FR 33379), and on July 14, 1997, the agency presented several OTC labeling issues to FDA's Nonprescription Drugs Advisory Committee.

In December 1997 and February 1998 the agency published two studies of OTC labeling formats ("Evaluation of Revised Formats for OTC Drugs" (62 FR 67770, Dec. 30, 1997) and "Evaluation of Proposed OTC Label Format Comprehension Study" (63 FR 7331, Feb. 13, 1998)), and re-opened the administrative record to allow for comment on these studies. CHPA filed extensive comments on the proposed rule as well as the two studies. On March 17, 1999, after carefully considering the comments and all relevant information, FDA issued the final rule on OTC labeling (64 FR 13254; Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201).

Following publication of the rule, the agency held a series of "feedback" and "workshop" meetings, to help the industry begin its transition to the new labeling format. These included public meetings on April 23, June 29, August 24, September 17, and November 23, 1999. At each of these meetings, and in a series of letters to the agency (attached to CHPA's petition), CHPA raised a variety of questions and concerns about the rule. CHPA made a detailed presentation at the June 29 meeting recommending that the agency allow the use of columns to present required information. At the August meeting, CHPA and CTFA raised concerns about the impact of the rule on the use of certain color combinations or "trade dress" in OTC drug and drug-cosmetic packaging. And, at the September and November meetings, CHPA focused in particular on type size issues and other concerns associated with small package products.

On October 1, 1999, CHPA submitted its petition (Docket No. 98N-0337/CP2) seeking a two year stay of the primary implementation date for the rule, and on October 22, 1999, CTFA submitted its petition (Docket No. 99P-4617/CP1) requesting essentially the same relief as CHPA.

On December 1, 1999, FDA issued a notice of availability of a draft guidance titled "Labeling of Over-the-Counter Human Drug Products Using a Column Format" (64 FR 67291), to address questions regarding the use of columns under the new format. On January 3, 2000, FDA issued a technical amendment to the rule to address, among other points, confusion over the use of "light" and "dark" shades of print and the related "trade dress" issue (65 FR 7).

II. Analysis

A. Columns

The labeling format adopted by the agency in the proposed and final rule generally favors a vertical presentation, to enhance readability, minimize the potential for confusion, and facilitate the side-by-side comparison of products. CHPA has asked for additional time to discuss whether the required labeling may be presented using a column format, including the use of "columns within columns." For example, after the agency published the final rule, CHPA recommended at several feedback meetings that manufacturers should be permitted to divide the information under each "Drug Facts" heading into columns.

On December 1, 1999, the agency issued a draft guidance document showing how the required labeling may be presented in a column format, in a manner that is consistent with the requirements of the final rule. 64 FR 67291. The guidance notes, however, that the "columns within columns" approach recommended by CHPA generally would not be permitted under the rule. Comments on the guidance were due January 31, 2000, and the agency intends to finalize the guidance as quickly as practicable.

The agency does not agree with CHPA that the request for "clarification" on the use of columns warrants a further extension of the primary implementation date. As shown in the draft guidance, the final rule permits the use of columns, provided the essential structure and flow of the "Drug Facts" panel is retained. The agency also notes that CHPA did not raise in its comments to the proposed rule the various ways in which it now seeks to use columns to present required drug labeling.[3] The procedurally appropriate step, if CHPA believes the rule should be

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[3]According to the petition, CHPA and other commentators "referred to columns" in comments to the proposed rule. Pet. at 8. CHPA did not, however, direct the agency to any specific discussion of this issue in the comments. CHPA's "Guidelines for OTC Labeling" include a brief description of the use of columns. In one footnote in CHPA's lengthy written

amended to allow more ways to use columns, would be to file a petition under 21 CFR 10.25(a).

B. Trade Dress

The agency believes the technical amendment document, published on January 3, 2000 (65 FR 7), resolves the questions that CHPA and others raised, following publication of the final rule, about the use of certain light on dark combinations of print. Therefore, an extension of the primary implementation date is not needed to allow for further discussion of this issue.

C. Type Size

The final rule requires a minimum type size of 6 points when presenting information in the "Drug Facts" labeling. 21 CFR 201.66(d)(2); *see generally* 64 FR at 13264-65. Since publication of the rule, CHPA has made several presentations on the issue of type size. CHPA estimates that as many as 30 percent of OTC stock keeping units cannot comply with the rule, and that type size is the most significant factor in determining whether the new labeling will fit onto an existing package.

Accordingly, CHPA has asked the agency to delay implementation of the rule to consider the use of smaller type sizes, especially for small packages. CHPA has argued that data in the record support a minimum type size of 4.5 points. Also, CHPA insists the agency lacks an adequate basis to require a 6 point minimum. Finally, CHPA has continued to raise the need for "type size parity" across all FDA regulated products. *See, e.g.*, Ex. 1; Ex. 2 at 6, slide 12. For the reasons discussed below, the agency does not agree that additional time is needed to consider type size issues.

1. General Factors

FDA has been considering the issue of type size for OTC drug products since at least 1990, when the Pharmacists Planning Service (PPS) petitioned FDA to set minimum standards for OTC drug labeling. Among other things, the petition emphasized that significant numbers of older adults have been hospitalized due to adverse drug reactions involving OTC drugs, and that most people (especially the elderly) are unable to read the print on OTC drug labeling. 62 FR at

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comments to the proposed rule, columns were listed as one many factors that may affect readability. The agency, however, found no substantive discussion by CHPA of the use of columns or the idea of allowing information under certain headings to be divided into columns ("columns within columns"). None of the labels appended to CHPA's comments, in which CHPA suggested modifications to FDA's proposed format, shows the use of "columns within columns." *See* CHPA comments, App. E. The "Recommended Format" submitted by CHPA with its comments, App. F, does not show or suggest the use of columns.

9028.

The issue of assuring readability for elderly consumers has been a significant consideration throughout this process. Although the elderly comprise 12 to 17 percent of the population, they consume about 30-50 percent of all drug products. 62 FR 9024, 9027. As discussed in a 1994 study, a significant number of elderly consumers (60 yrs or older) could not adequately see the print on certain OTC product labels due in part to small type sizes and horizontal letter compression. *See* 62 FR at 9028 (*citing* Ex. 3); *see also* Sept. 29, 1995, Public Hearing on Over-the-Counter Drug Labeling Transcript at 31, FDA Docket No. 95N-0259 (hereafter Transcript) ("[T]he elderly are more likely to use over-the-counter medications, more likely to have a higher incidence of medical conditions that may be adversely affected by the inappropriate use of medications, and more likely to be taking other medications that may have adverse interactions with certain over-the-counter medications.").

Second, the goal of this proceeding has been to set standards for clear, consistent, easy-to-read drug labeling, and to minimize the "cognitive load" that drug labeling places on lay consumers. *See, e.g.*, 64 FR at 12355. Under section 502(c) of the Federal Food, Drug, and Cosmetic Act, drug labeling must be sufficiently prominent and conspicuous "as to render it *likely to be read and understood* by the ordinary individual . . ." 21 U.S.C. 352(c) (emphasis added); *see* 64 FR 9043. Marginal type sizes, or type sizes that are legible only at threshold levels, make it *less likely* that a consumer will begin to read the labeling, let alone read it thoroughly.

Third, as discussed below, the agency carefully considered industry practices in setting a minimum type size for OTC drug labeling, to help ensure the adoption of an attainable standard.

2. CHPA's Approach

CHPA's central study in support of the argument that 4.5 point type is an appropriate minimum standard for OTC drug labeling is Sidney Smith's 1979 article, "Letter Size and Legibility" (attached as Ex. 4).[4]

Smith studied "display legibility" using a variety of test materials, none of which appears to have included drug labeling. Ex. 4 at 665. Some of Smith's samples consisted only of a single word. *Id.* at 667. Moreover, the subjects in the study were asked only to identify the

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[4]CHPA referenced the Smith study in its comments to the proposed rule (*see* CHPA comments to proposed rule, App. H.) and in correspondence with the agency prior to the proposed rule. *See, e.g.*, Ex. 5. Although Smith and the other studies discussed in this section are already part of the record of this proceeding, the agency them as exhibits to this response, for the convenience of the reader.

absolute "legibility limit" for a given piece of display material. *Id.* at 666 ("The only measure taken was the legibility limit."). Viewers were not asked to specify a comfortable or preferred viewing distance, nor were they asked to identify the distance from which the material could be read with ease. Also, Smith did not record the age of his test subjects. There is even some suggestion that most may have been under 30 years of age. *Id.* at 668.

In contrast, the focus of this proceeding has been on labeling that consumers are *likely* to read and understand, from beginning to end, rather than on the threshold levels at which consumers can first begin to see printed material. *See* 21 U.S.C. 352(c). There is an important distinction between what a consumer is able to see, and what a consumer is likely to try to read – from beginning to end, with minimal error. As Smith cautioned:

> In practical display applications, however, it is not wise to design to the limits of visual acuity. An engineer will not design a bridge to meet minimum loads, but instead multiplies the strength of supporting trusses by some safety factor so that the bridge can be crossed with greater confidence. A display designer should also include some safety margin, specifying a letter size large enough to be read with confidence.

Ex. 4 at 662 (emphasis added).

Finally, following publication of the final rule, CHPA has continued to reference Smith for the idea that "98% of test subjects could read 4.5 point type at a distance of 13 inches." Ex. 6 at 7. In fact, Smith found that 98 percent of his test subjects could read copy that subtended a visual angle of 0.0046 radians.

According to CHPA, a visual angle of 0.0046 radians corresponds to a letter height of 0.06 inches at a viewing distance 13 inches,[5] and a letter height of 0.06 inches corresponds to a point size of 4.5. Ex. 5 at 2. However, a type size of about 6 to 8 points would be needed to present text that is generally 0.06 inches in height. This is because, as CHPA has stated, letters set in 4.5 point type are *not* 0.06 inches high.[6] *Id.* CHPA's submissions to the agency state that point size is a measure of the total height from the bottom of the lowest letter to the top of the highest letter, and that the upper case letters in 4.5 point type are usually only .042 inches or about 3 points. *Id.* Lower case letters in 4.5 point type would be even smaller – about half the

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[5]Although CHPA assumes a viewing distance of 13 inches, other materials cited by CHPA suggest 16 inches as the appropriate benchmark for "reading distance." Ex. 5 at 3 (citing Holt, G., *et al..*, "OTC Labels: Can Consumers Read and Understand Them?" 11 *American Pharmacy* 51 (Nov. 1990)). Using 16 inches, the letter height would be 0.0736 inches.

[6]Type sizes are designated in units called points. There are approximately 72 points to one inch. Each point measures 0.0138 of an inch.

point size or 0.03 inches. Therefore, to achieve the level of legibility that CHPA relies on from the Smith study, one would need to use text that is more than 6 points (assuming a viewing distance of 13 inches and the use of all upper case letters); or 8 points (assuming a viewing distance of 13 inches and the use of primarily lower case letters)[7]. Added to that, Smith found that letter sizes intended for close viewing, such as consumer labeling, may need to be larger in size than one would derive from a measure of the limits of visual acuity. *Id.* at 668.[8]

For these reasons, the agency disagrees with CHPA that the Smith study supports the use of 4.5 point type in OTC drug labeling. Indeed, Smith would support the use of a larger type size (6 point *or greater*) for consumer-directed drug labeling.

CHPA has also directed the agency to "the definition of visual acuity" to support the use of 4.5 point type in OTC drug labeling. *See, e.g.*, Ex. 5; Ex. 7. According to CHPA, a person with 20/20 vision can read text 0.019 inches high at a distance of 13 inches (equal to 1.7 point type), a person with 20/40 vision can read text 0.037 inches high (equal to 3.3 point type), and a person with 20/55 vision, according to CHPA, would be able to read 4.5 point type. *See* Ex. 5 at 3; *see also* Ex. 7 at 1.

For reference, the following sentences are set in 1.7, 3.3, and 4.5 point type:[9]

This sentence is in 3.3 point Times New Roman type.

This sentence is in 4.5 point Times New Roman type.

Each of these type sizes – if one accepts CHPA's assumptions – represents the threshold limit at which a person with a given visual acuity can begin to see text. They do not represent type sizes which can be read with ease. *See* Ex. 4 at 662 ("Design standards for visual displays generally

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[7]The OTC labeling rule requires primarily the use of *lower case* letters. *See* 21 CFR 201.66(d)(1).

[8]Smith also found that 100 percent of his subjects could read a letter size of 0.007 radians. *Id.* at 667. Using CHPA's method of converting this figure to a point size, Smith found that 100 percent of his test subjects were able to read 6.6 type at a distance of 13 inches. If one adjusts for the use primarily of lower case letters and a viewing distance of 16 inches, one would need to use a type size of more than 12 points to attain the level of legibility found by Smith.

[9]The following sentences are set in 6, 8, and 10 point type:

This sentence is in 6 point Times New Roman type.

This sentence is in 8 point Times New Roman type.

This sentence is in 10 point Times New Roman type.

recognize the need for a safety margin, and specify letter sizes larger than those at the limits of visual acuity."). Moreover, if one adjusts for a standard reading distance of 16 inches, and takes into account the use of primarily lower case text, each of these types sizes would have to be adjusted *upward*. The agency also notes that type size is only one factor that determines readability (*see* 62 FR at 9028), and that OTC labeling – which often consists of extensive and complex text – can be especially demanding for the reader.[10]

At best, CHPA's approach may help to establish a base from which to develop specific minimum type sizes for specific categories of products. As discussed below, the agency has allowed the use of the smallest readable type size in certain contexts (*see* section II.C.4, below). For OTC drug labeling, however, there is ample basis to require a larger size.

3. The Industry Standard

A key starting point for FDA in setting an appropriate minimum type size for OTC drug labeling was to consider current industry practice. At the agency's September 1995 public hearing, CHPA testified that most of the OTC drug industry had already adopted 6 points "*or better*" as the standard:

> We have done a label survey of our members looking at 2,000 labels and over 95 percent were at six point or better, and I think one of the practicalities is that there is a huge amount of information that is required on some of these labels. The particular diphenhydramine prototype that is in Appendix C [is] done at around six points, if you do that at seven points [it] will not fit the package. So, we recommend adopting the current industry practice."

Transcript at 108 (emphasis added).[11]

The agency, in turn, incorporated the industry standard into the OTC labeling rule after hearing additional testimony and after reviewing several studies confirming the readability of 6

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[10]In contrast, a study submitted by the American Pharmaceutical Association with a comment to the proposed rule evaluated the readability of 9 OTC drug labels with type sizes ranging from 4 to 11 points. Ex. 8. The study found that subjects needed at least 20/30 vision to read OTC drug labeling in 4 point type and 20/40 vision to read labeling in 6 point type. Only one of the labels (presumably, a label set in 11 point type) could be read accurately by those with a visual acuity of 20/50. Ex. 8 at 51.

[11]In its written submission to the public hearing, CHPA noted that "as an absolute minimum, 4.5 print type is reasonable for OTC labels, though not often used. Six point type is commonly used and preferred." Ex. 9 at 17.

point type for OTC drug products. For example, the National Consumers League (NCL) testified at the September 1995 hearing on an "investigative survey" of OTC drug labeling. In the study, 60 adults were asked to assess the readability of OTC products ranging in size from 4.0 to 6.5 point type. Ex. 10 at 3. As the agency noted in the rulemaking, NCL found that only 32 percent of the subjects age 51 and older were able to read OTC drug labeling set in 4.5 point type. 64 FR at 13265. Among the labels tested by NCL, the one set in 6.5 point type proved best, with 75 percent of the subjects age 51 and older, and 94 percent of the subjects under age 51, able to read it. On the other end of the spectrum, none of the subjects age 51 and older was able to read one of the labels set in 4 point type, and only 25 percent of the subjects under age 51 were able to read the label. Ex. 10 at 8. Thus, the NCL survey raises concerns about the readability of type sizes around a 4.5 point range and, at the same time, supports the use of type sizes in the 6.5 point range.[12]

The Watanabe study, cited by the agency in the rulemaking, also supports the use of a 6 point or better type size. Dr. Watanabe sampled 92 consumers, 60 years of age and older, using three labels – two set in 3.3 point type and one set on 6.7 point type. Ex. 3 at 33; *see also* 64 FR at 13265. In addition to showing that horizontal letter compression is a significant factor in determining readability, the Watanabe study concluded that a vertical type size of at least 6.7 points should be used in OTC drug labeling.[13]

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[12]At the November 23, 1999, feedback meeting, CHPA stated that the NCL study supported the use of less than 6 point type. Ex. 2 at 6, slide 11. The 5 point label tested in the NCL survey performed at the same level as one of the labels set in 6 point type. Forty-eight percent of the subjects age 51 and older either could not see the text on either label or found it too hard to read. Factors, such as color contrast, layout, or letter compression, may have accounted for these results. However, a second label tested by NCL, set in 6 point reverse type significantly outperformed the other labels. Sixty-eight percent of the older subjects and 91 percent of the younger subjects were able to read it. Ex. 10 at 9.

[13]At the November 23, 1999, feedback meeting, CHPA asserted that the Watanabe study "showed little difference in readability between 6.7 and 3.3 point type." Ex. 2 at 6, slide 11. We disagree. In a comparison of one of the 3.3 point labels to the 6.7 point label, Dr. Watanabe found that approximately 30 percent of the subjects were unable to either start *or finish* reading the 3.3 point label. Only 2 percent were unable to read the 6.7 point label. In a comparison of the other 3.3 point label with the 6.7 point label, Dr. Watanabe found only a small statistical difference in readability, concluding that the horizontal letter compression on the 3.3 point label compensated significantly for the smaller type size. However, Dr. Watanabe also concluded that "subjective observations by both subjects and researchers indicate that greater effort was expended in reading the smaller print [on this label]," and that "[t]his suggests that letter size approximating the [6.7 point type size] should be used." Ex. 3 at 35.

The agency also received numerous comments from consumers, consumer groups, and health professionals in favor of adopting 6 point or larger as the minimum standard. *See, e.g.*, FDA Docket No. 96N-0420, C103; C104; C467. Consumer preferences and comments are significant in this proceeding, given the statutory directive to develop labeling that consumers will be "*likely*" to read.

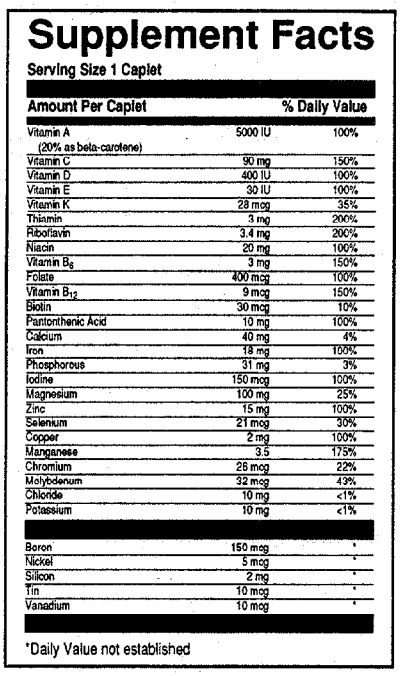
4. "Parity"

Finally, at the November 23, 1999, feedback meeting and at several other public meetings following the final rule, CHPA has emphasized the need for "consistency and fairness across FDA regulated consumer products." As noted in comments to the proposed rule, the agency allows certain dietary supplement products to use a minimum 4.5 point type. 21 CFR 101.36(i). The agency has also allowed letters no less than 1/16th of an inch for the listing of ingredients in cosmetic products, or 1/32 of an inch in limited circumstances. 21 CFR 701.3(b) and (p).

The agency carefully considered this issue in the final rule and did not find it to be decisive. 64 FR at 13265. As the agency outlined in the rule, factors such as the nature and quantity of the information required, and the manner in which the information is presented, may allow for the use of different labeling specifications. In some contexts, there is often little required information presented on the labeling (either a few words or a single sentence), and there is adequate white space to enhance readability, putting less of a demand on the user to read the information.

This point is illustrated below. Figure 1 shows a multi-ingredient dietary supplement product with the required text presented in 4.5 point type, compared with a multi-ingredient OTC drug product. The OTC drug product follows the modified format permitted under 21 CFR 201.66(d)(10), except that for purposes of illustration the drug product uses 4.5 point type to present the required text rather than the required 6 point minimum. Figure 2 compares the multi-ingredient OTC drug product in 4.5 point type versus 6 point type. Figure 2 illustrates the benefit of a larger type size in OTC drug labeling. Both figures use optimal color contrast (black text on a non-glossy white background).

Figure 1

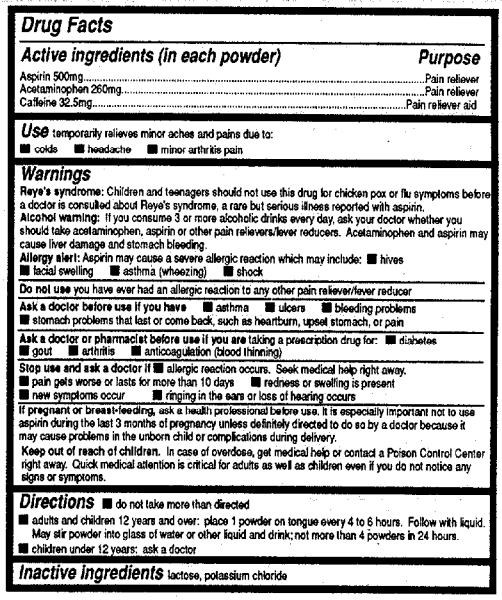


Supplement Facts

Serving Size 1 Caplet

Amount Per Caplet		% Daily Value
Vitamin A (20% as beta-carotene)	5000 IU	100%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Vitamin K	28 mcg	35%
Thiamin	3 mg	200%
Riboflavin	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B_6	3 mg	150%
Folate	400 mcg	100%
Vitamin B_{12}	9 mcg	150%
Biotin	30 mcg	10%
Pantonthenic Acid	10 mg	100%
Calcium	40 mg	4%
Iron	18 mg	100%
Phosphorous	31 mg	3%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	15 mg	100%
Selenium	21 mcg	30%
Copper	2 mg	100%
Manganese	3.5	175%
Chromium	26 mcg	22%
Molybdenum	32 mcg	43%
Chloride	10 mg	<1%
Potassium	10 mg	<1%
Boron	150 mcg	*
Nickel	5 mcg	*
Silicon	2 mg	*
Tin	10 mcg	*
Vanadium	10 mcg	*

*Daily Value not established



Drug Facts

Active ingredients (in each powder) — **Purpose**

Aspirin 500mg ..... Pain reliever
Acetaminophen 250mg ..... Pain reliever
Caffeine 32.5mg ..... Pain reliever aid

Use temporarily relieves minor aches and pains due to:
■ colds ■ headache ■ minor arthritis pain

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported with aspirin.
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen, aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.
Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

Do not use you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have ■ asthma ■ ulcers ■ bleeding problems ■ stomach problems that last or come back, such as heartburn, upset stomach, or pain

Ask a doctor or pharmacist before use if you are taking a prescription drug for: ■ diabetes ■ gout ■ arthritis ■ anticoagulation (blood thinning)

Stop use and ask a doctor if ■ allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts for more than 10 days ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

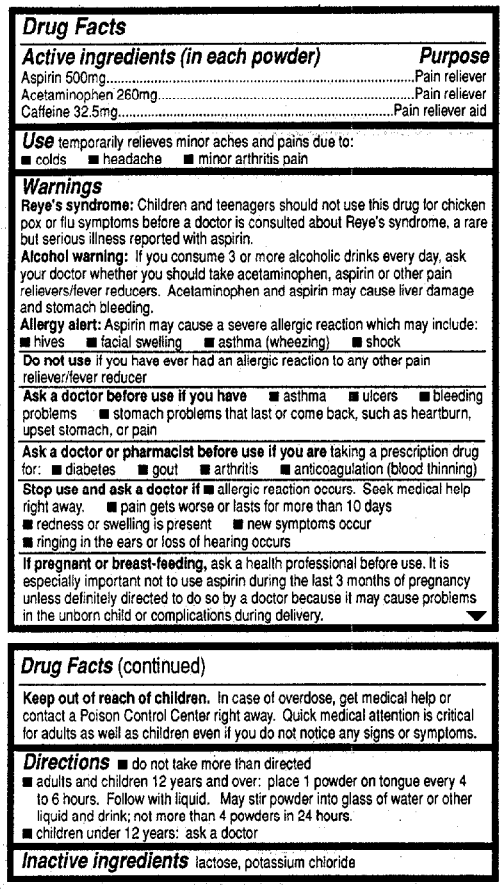
Directions ■ do not take more than directed
■ adults and children 12 years and over: place 1 powder on tongue every 4 to 6 hours. Follow with liquid. May stir powder into glass of water or other liquid and drink; not more than 4 powders in 24 hours.
■ children under 12 years: ask a doctor

Inactive ingredients lactose, potassium chloride

14 point Helvetica Regular Bold Title
6 point Helvetica Narrow Bold Headings
6 point Helvetica Narrow Subheadings
4.5 point Helvetica Narrow Text
5.5 point Leading

8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

Figure 2



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Drug Facts (continued)

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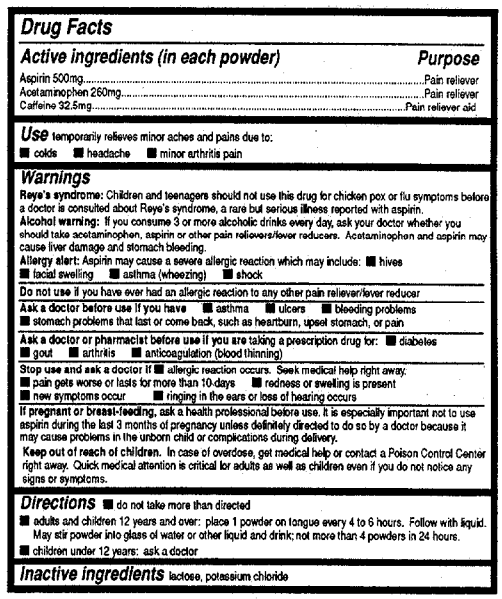
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6.5 point Leading



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Inactive ingredients lactose, potassium chloride

8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

As the agency found in the final rule (and as illustrated here), the overall "Supplement Facts" layout, including the tabular style and the limited amount of explanatory text, allows for the use of a smaller type size in limited circumstances.

The agency also notes that in other instances it has required 6 point or larger type. For example, the agency established a 10 point minimum type size for approved patient labeling for human prescription drug and biological products (*i.e.*, "Medication Guides"). 21 CFR 208.20(a)(4); *see also* 21 CFR 610.62 (requiring the use of 12 point and 18 point type when designating antibodies in certain biologic labeling). The minimum type size for food nutritional labeling for most products is 8 point type for certain information on the label and 6 point type for all other information. Small packages (less than 12 sq. inches) may opt not to present nutritional information. *See* 21 CFR 101.9(j)(13)(i). However, small packages that present nutrition information must use a minimum of 6 point type or all upper case letters of 1/16 inches in height. 21 CFR 101.9(j)(13)(i)(B).

Finally, for various warnings and other statements required on some FDA-regulated products, a type size or letter height of 1/16th of an inch has been required. *See, e.g.*, 21 CFR 101.93(e) ("letters of a type size no smaller than one-sixteenth inch"); 310.516(c)(1) ("minimum letter size shall be one-sixteenth of an inch in height . . . letter heights pertain to the lower-case letter 'o' or its equivalent that shall meet the minimum height standard"); 701.3(b) ("letters not less than 1/16 of an inch in height"); 740.2(a) ("in no case may the letters and/or numbers be less than 1/16 inch in height.").[14]

In short, the agency considered the labeling specifications for other product categories in developing the final OTC labeling rule. The agency also considered, however, the unique demands of OTC drug labeling, along with the strong trend in the OTC drug industry toward 6 point type, and determined that a type size larger than that allowed in limited circumstances for other categories of products such as dietary supplements was justified and reasonable.

* * *

The agency has carefully reviewed the issue of type size, including the points and materials CHPA highlighted in comments to the proposed rule and in correspondence and feedback meetings over the last several months. The agency concludes that there is no need to delay implementation of the rule to continue to consider this issue.

D. Single Use Packages, Convenience Packages, and Extended Text Labeling

The petition states that additional time is needed to resolve the labeling of single use and

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[14]Applying the analysis discussed in section C.2 of this response, if the minimum letter size permitted is 1/16 of an inch, a type size as large as 8 or 9 points may be needed in some instances to ensure that the smallest letter is no smaller than 1/16 of an inch. The limited instance in which the agency has allowed 1/32 inch type (21 CFR 701.3(p)) may require about 4.5 point type.

other convenience packages, and to address technical issues associated with the use of "extended text labeling." According to presentations made by CHPA at several recent feedback meetings, single use products and "convenience-sized" products in particular are having difficulty fitting the new format onto existing packaging. These categories, according to CHPA, account for between 1 and 2 percent of the OTC market. Ex. 2 at 13, slide 26.

The agency anticipated in its final rule that there would be a small percentage of products that would have difficulty integrating the new format into existing packaging and labeling. The agency's research leading up to the final rule estimated that 8 percent of currently marketed OTC drug products would require an increase in labeling space to accommodate the new format. As a result, the agency included within its final economic impact analysis an estimate of the additional re-packaging costs that some firms may bear as they seek to integrate the new format. *See generally* 64 FR at 13282-83; Eastern Research Group, Inc., "Cost Impacts of the Over-the-Counter Pharmaceutical Labeling Rule," in Docket No. 96N-0420.

CHPA acknowledges there are packaging options for single use and convenience products that would permit use of the new labeling. Ex. 2 at 14, slide 27. Several of these options are commonly in use, such as bubble packs mounted on hang cards and the bundling of rolled products in blister packs. CHPA, however, has asked for a series of follow-up meetings to discuss these and other options, and has also asked for additional time to discuss whether single use or convenience products may be eligible for type size or other format exemptions. Ex. 2 at 14, slide 28.

For the reasons discussed in section II.C. above, the agency does not believe that a type size exemption requires further consideration at this time, particularly where there are several packaging options available that would allow for presentation of the required format using the standards in the final rule. The agency does expect, however, that the column format option described in the December 1, 1999, draft guidance document may help some manufacturers maximize their available labeling space.

For those manufacturers who, as a result of the new labeling rule, must implement a change in package size or configuration, the agency intends to outline in a forthcoming guidance several circumstances in which the agency is likely to provide additional time (*i.e.*, a "deferral") under 21 CFR 201.66(e) in which to make such changes. The final rule allows for product-specific exemptions or deferrals, upon a showing that one or more of the labeling requirements is inapplicable, impracticable or, for a particular product, contrary to public health or safety. 21 CFR 201.66(e). The agency stated in the final rule that it does not expect to routinely grant an exemption or deferral solely because a product claims to be too small to meet the requirements of the rule. 64 FR at 13268. This is consistent with the agency's overall goal of ensuring that all OTC drug labeling, irrespective of package size, is clear and readable and is "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21

U.S.C. 352(c). It is also consistent with the agency's estimate that any package size changes that would be needed as a result of this rule would either be very limited (*e.g.*, increasing the dimensions of an existing package by a small fraction), or could be accomplished by integrating commonly used techniques, such as the addition or extension of a fifth panel or the use of a placard and bubble-pack. *See* 64 FR at 13268, 13283.

The agency will, however, consider good faith, product-specific requests for a deferral of time for the purpose of completing a change in container size or packaging, in order to meet the requirements of the rule. For example, if a firm requires additional time to complete stability testing on a new immediate container, where it is shown that the existing container could not comply with the new format, the agency would consider a time-limited deferral. The agency will provide additional information in a forthcoming guidance on the use of the deferral process to obtain more time to complete a change in packaging. The agency expects to discuss in the guidance the use of the deferral process by those who wish to use an extended text mechanism that may require new machinery or new studies, such as a peel back panel, to meet the requirements of the rule. Following issuance of a draft guidance, the agency will solicit written comments before issuing a final document.

Through these additional steps, the agency believes it will be able to address concerns regarding the use of the new labeling format on single use and convenience products, and the use of extended text labeling. The petition has not shown that a further extension of time to allow for consideration of these issues is required.

E. Exemptions and Deferrals

The petition asks for additional time while the agency resolves questions that have been raised regarding the exemption and deferral process allowed under section 201.66(e) of the final rule (21 CFR 201.66(e)).

Although the petition does not elaborate on this point, the agency is aware that CHPA and CTFA have asked in public meetings and in correspondence for guidance on the procedures to be followed in requesting an exemption under § 201.66(e). Among other things, CHPA and CTFA have inquired as to the length of time it will take the agency to answer a request for exemption, and what steps might be taken to expedite the review of a request. They have also asked whether an appeal process is available, or whether the initial decision on the request for exemption represents "final agency action."

Second, they have asked for guidance on the standard the agency will apply in reviewing requests for exemption, and whether there are certain types of requests that are likely to receive a favorable response from the agency. CHPA and CTFA have also asked whether there are categories of exemptions that could be handled through an abbreviated process, such as through

the submission of a "notification" to FDA.

Finally, CHPA and CTFA have expressed concern that the exemption process may require the submission of trade secret or confidential commercial information, and that the process outlined under § 201.66(e) does not provide a mechanism for protecting such information from disclosure.

The agency is working on a forthcoming guidance document that will provide additional information in response to these questions. The agency notes, however, that lack of a guidance has not prevented several companies (both small and large) from submitting applications for exemption. The agency has already processed a number of these requests and is prepared to continue doing so as expeditiously as possible.

F. Other Issues

CHPA has also raised a number of other issues with the agency since publication of the final rule. As noted in the petition, CHPA has asked whether the agency would grant exemptions from the "Drug Facts (continued)" requirement, to help products fit the new labeling within existing packaging. CHPA has also asked for clarification about the placement of a manufacturer's telephone number on the labeling.

Neither of these issues warrant a further extension of the primary implementation date. For those few products that may benefit from an exemption from the "Drug Facts (continued)" labeling requirement (21 CFR 201.66(c)(1)), or from the required location for the placement of a telephone number (21 CFR 201.66(c)(9)), the agency will consider product-specific requests through the exemption process allowed under section 201.66(e). After the agency has gained additional experience in reviewing specific applications for exemption, it will consider whether additional guidance would be helpful.

III. Conclusions

Most of the issues raised in the petition (columns, the exemption process, the labeling of single use and convenience products) have been addressed or will soon be addressed through the agency's guidance process. *See generally* 62 FR 8961 (Feb. 27, 1997). One issue (trade dress) was addressed through an amendment to the final rule. The remaining issues (*e.g.*, the placement of a telephone number or the use of the "Drug Facts (continued)" title) do not present a significant obstacle toward industry-wide implementation of the new labeling format, as demonstrated by the large numbers of products that are able to comply with the rule. Indeed, as the petition suggests and as CHPA has noted at several recent feedback meetings, the new labeling format can be incorporated into a large majority (70-80 percent) of existing products.

Based on the agency's evaluation, we believe the figure is significantly higher.[15]

For these reasons, the agency concludes that a stay of the rule, or a blanket extension of two years, is excessive and is not consistent with the public's interest in having clear, readable OTC drug labeling. However, in recognition of the fact that there are several guidance documents that may prove helpful in the transition to the new format, and that at least one (on exemptions and deferrals) has yet to issue, the agency concludes that an extension of the May 2001 primary implementation date by one year to May 16, 2002 (and the corresponding implementation date for low volume products to May 16, 2003) is justified.

The agency has worked closely with CHPA to help ensure that OTC drug product labeling is legible and that the final rule is appropriate for the marketplace. We look forward to continuing to have candid, productive discussions, and to working with CHPA toward the shared goal of providing consumers with clear, concise, easy-to-read labeling.

Sincerely yours,

William Hubbard

William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

cc: Robert P. Brady
Hogan & Hartson

[15] *See, e.g.*, Ex. 11 at 9; *compare* 64 FR 13282-83.

Exhibit List
FDA Petition Response
Over-the-Counter Drug Labeling
Docket No. 98N-0337/CP2

Exhibit 1.	September 16, 1999, CHPA Type Size and Exemption Process Memorandum
Exhibit 2.	November 23, 1999, Slide Presentation by R. William Soller, Ph.D., and William Bradley, CHPA, at FDA Feedback Meeting on OTC Label Content and Format
Exhibit 3.	Watanabe, R. K., "The Ability of the Geriatric Population to Read Labels on Over-the-Counter Medication Containers," 65 *Journal of the American Optometric Assoc.* 32 (1994)
Exhibit 4.	Smith, S., "Letter Size and Legibility," 21 *Human Factors* 661 (1979).
Exhibit 5.	July 29, 1992, Letter from William Bradley, CHPA, to William E. Gilbertson, FDA
Exhibit 6.	November 2, 1999, Memorandum and Slide Presentation from CHPA to Charles Ganley, FDA
Exhibit 7.	October 6, 1997, CHPA Comments to Proposed Rule, Appendix H
Exhibit 8.	Cheung, A., et al., "Visual Acuity in Reading Nonprescription Drug labels," *Can. Pharm. J.* 47 (Dec./Jan. 1995).
Exhibit 9.	September 29, 1995, Comments by CHPA, Public Hearing on OTC Labeling, TS10 to FDA Docket No. 95N-0259
Exhibit 10.	August 5, 1991, Comments of the National Consumers League on Print Size and Style of Print for Over-the Counter Drug Products, C57 to FDA Docket No. 90P-0201
Exhibit 11.	June 29, 1999, Slide Presentation by R. William Soller, Ph.D., and William Bradley, CHPA, at FDA Feedback Meeting on OTC Label Content and Format

The attachments to this document may be viewed at:

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